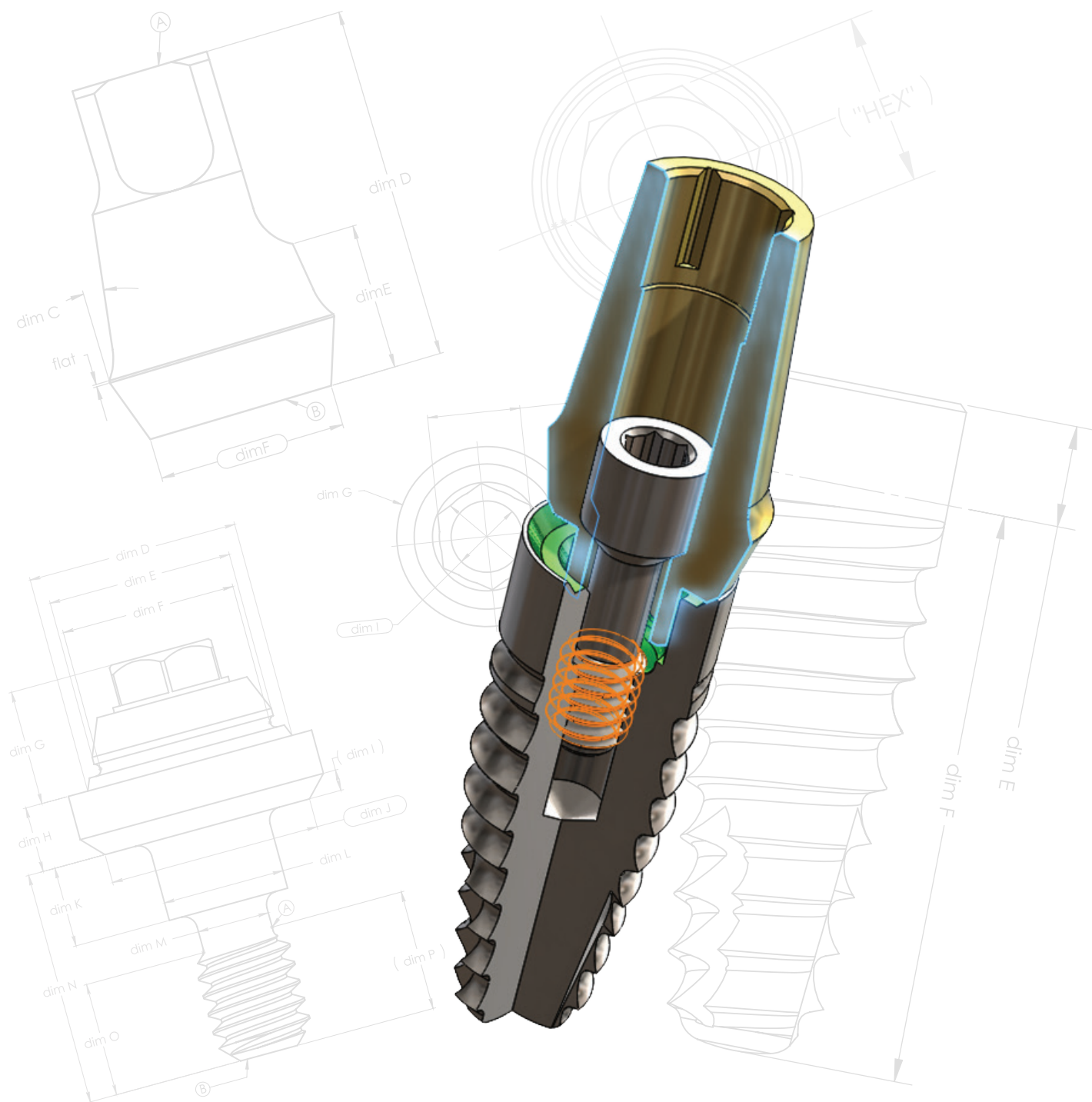


Unique Design Advantages of the BioHorizons Conical Internal Hex Connection

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Executive Summary

As implant dentistry evolves toward superior and faster outcomes, complications such as prosthetic screw loosening and abutment fracture remain prevalent concerns for many commercially available implant designs. The joint strength, lateral stability and rotational stability of prostheses are all dependent on the implant-abutment interface.¹ Understanding the science behind the different designs on the market today is crucial for dental implant surgeons to make an informed choice of what system to use. This document serves as an engineering review of the BioHorizons internal connection to help dentists select the best implant and connection to meet their needs.

The BioHorizons conical, internally hexed connection features a number of unique design advantages focused on strength, durability and usability. The mating surfaces of the implant, abutment and abutment screw create a strong and durable precision fit as well as a predictable seal that isolates the inside of the implant from the oral biological environment. The BioHorizons connection features Spiralock® superior fastening technology to significantly increase the strength of the connection and reduce abutment screw loosening and fatigue failure. Strength and fatigue limits are also enhanced through the use of titanium alloy Ti-6Al-4V ELI.² Color-coded prosthetic components and implant connections make it easy to identify the different platforms and assemble the correctly sized componentry.

Introduction

Conical connections represent one of the fastest-growing segments of the dental implant market today.³ They offer a smaller micro-gap and higher level of mechanical stability than butt-joint connections. The lack of intimate fit between an implant and abutment can provide an area for bacterial growth which in turn can lead to inflammation, tissue recession and bone loss.³

In 2004, BioHorizons Implant Systems, Inc. introduced its conical, hexed connection in 3.5, 4.5 and 5.7mm platform sizes which very quickly became the company's most popular connection type. In 2010, a 3.0mm platform size was added and has also enjoyed much success. Currently, the BioHorizons conical, internally hexed connection is offered on a number of implant styles including: Internal, Tapered Internal, Tapered Plus, Tapered Tissue Level and Tapered 3.0 (Figure 1). To date, over 2 million implants using a conical, internally hexed connection have been sold by BioHorizons with a reported fracture rate of only 2 per 100,000 implants (or 0.002%).⁴

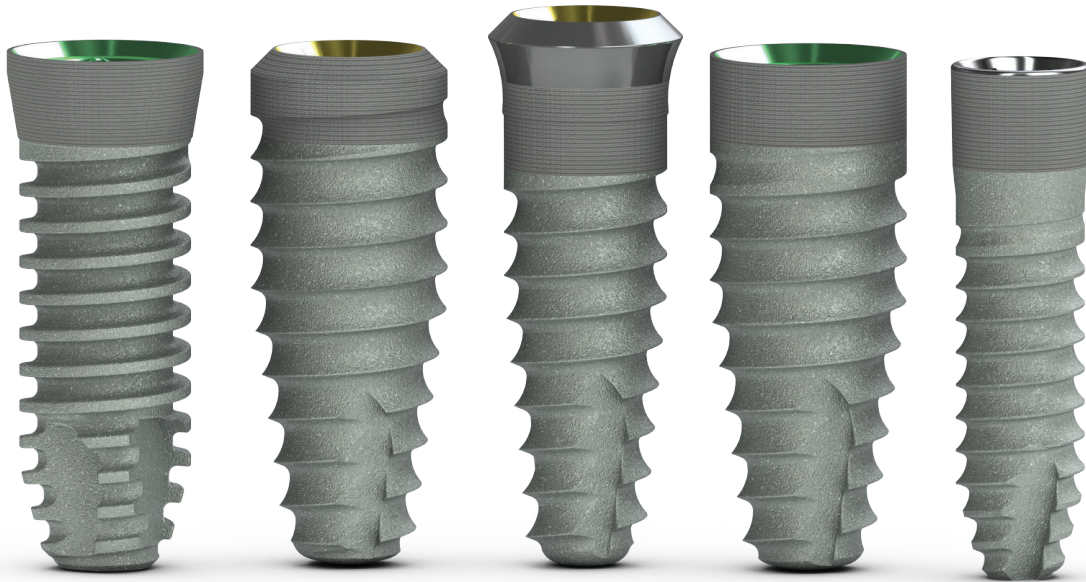


Figure 1: Internal, Tapered Internal Plus, Tapered Tissue Level, Tapered Internal and Tapered 3.0 Implant Systems all feature the BioHorizons conical, internally hexed connection.

The connection between the components of a dental implant system mimics a standard bolted connection where two parts, the implant and the abutment, are connected via a bolt (the abutment screw). The bolt (or screw) must be tightened to the proper torque based on the size and material of the components.⁵ Some of the key principles that should be considered in the design of a bolted connection are:⁶

1. Minimize load eccentricity. Components should be aligned to allow for a symmetrical transfer of load.
2. Maximize clamp force efficiency. The length of the bolt should be minimized to improve the clamping force.
3. Optimize torque value. The recommended bolt torque should be within the elastic zone of the bolt material.

The BioHorizons conical, internally hexed connection satisfies these principles and innovates beyond them to provide a predictable seal between the components.

OEM versus Clone Components

In implant dentistry, aftermarket or clone manufacturers represent their prosthetics as identical yet cheaper alternatives to OEM components. This can be misleading to clinicians and can create unintended risks in their implant restorations. Although BioHorizons internal hex components and other companies' internal hex components have been claimed by some to be interchangeable, the design and quality incorporated in these components are drastically different (Figures 2 & 3). Some of the issues identified with aftermarket abutments and screws include:

1. Incorrectly sized and toleranced dimensions lead to ill-fitting components, less efficient load transfer, increased strain, component and/or implant fracture.
2. Inappropriate seating of components resulting in open connections that create a breeding ground for bacteria growth, infection, tissue recession and bone loss.
3. Machining burs and poor surface finish that can affect component fit, implant-abutment junction seal and irritate soft tissues.
4. Lack of anodized color coding on prosthetics or incorrect anodized colors can lead to mismatched components.
5. Increased risk of periodontal pocketing and bone loss due to the absence of Laser-Lok microchannels.
6. Butt joint abutment screw connections which create a less favorable seal in screw channels compared to BioHorizons authentic conical connection.
7. Burs on the abutment's counter bore which can break away from the surface during screw placement and into the implant. The burs can also affect the seating of the screw.
8. Damage to the screw's internal hex edges which may cause the hex driver to slip and strip preventing the achievement of a proper torque load.
9. Only two full threads on the screw. For a solid engagement, three threads minimum are required. The number of threads plays a major role in achieving the necessary torque load.

Many of these aftermarket or clone abutments have not undergone evidence-based testing or trials. Important characteristics such as material composition, machining, surface finish and design are not well documented. Thus, self-proclaiming compatibility does not always guarantee proper tolerancing or even cleanliness of the components. This could increase the risk of potential complications such as bone loss, infections and fractures.

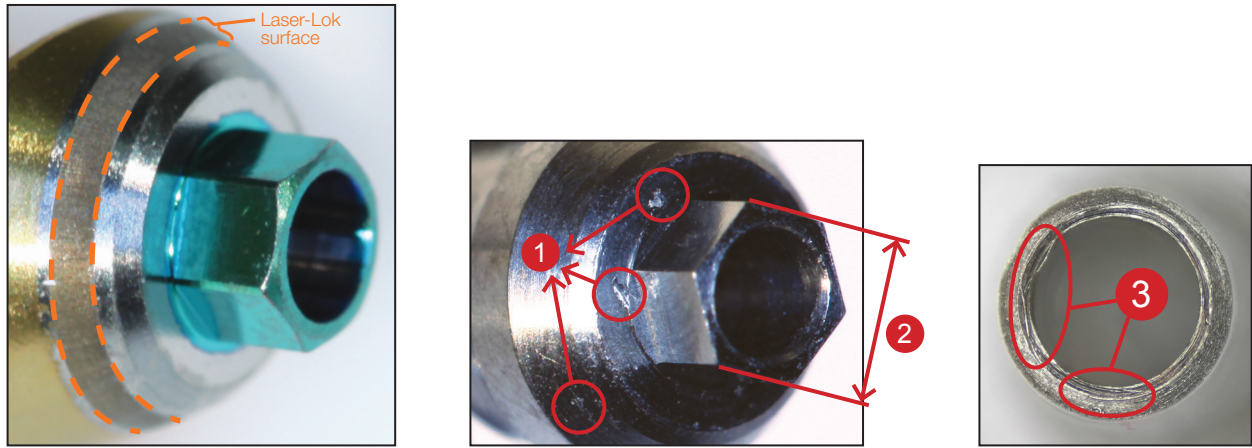


Figure 2: BioHorizons Authentic Abutment (left) versus aftermarket abutments (right two). Aftermarket abutments: (1) big machining burs on the entire surface and connection, (2) hex is oversized and not anodized to match implant, (3) burs on the abutment's counter bore where the screw is seated.

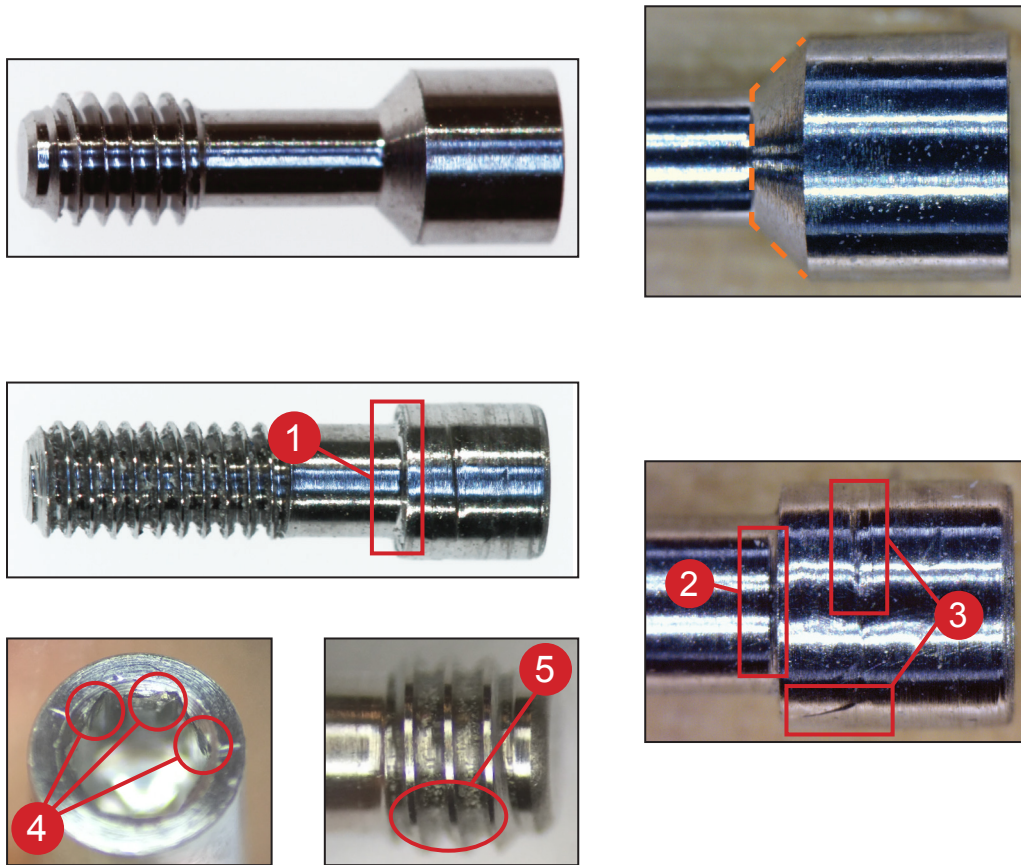


Figure 3: BioHorizons Authentic Screw (top) versus aftermarket screw (bottom). Aftermarket screws: (1) butt joint connection will not seat properly, (2) big edge break creates a weak point prone to material fatigue and fracture, (3) and (4) deep machining marks and damage to the hex indicate poor machining quality, (5) only two full threads which do not achieve the proper torque load.

BioHorizons Conical, Internally Hexed Design

Alignment Features

When mastication forces are applied to an implant-supported prosthesis, any misfit in the implant-abutment interface can have a drastic outcome on the mechanical behavior of the implant system.⁷ BioHorizons conical connection minimizes eccentric loading by incorporating two alignment features:

1. Conical connection between the implant and abutment

The alignment between the implant and abutment creates a conical seal upon abutment screw tightening (Figure 4). When the assembly is subjected to lateral forces and bending, the conical connection helps distribute the load efficiently between the abutment and implant. Furthermore, it provides sufficient interfacial

surface area allowing an improved resistance to lateral motion (i.e. perpendicular to the long axis of the assembly) and protection of the abutment screw from shear stresses. Thus, the stability of the system is not solely a function of the abutment screw.⁸

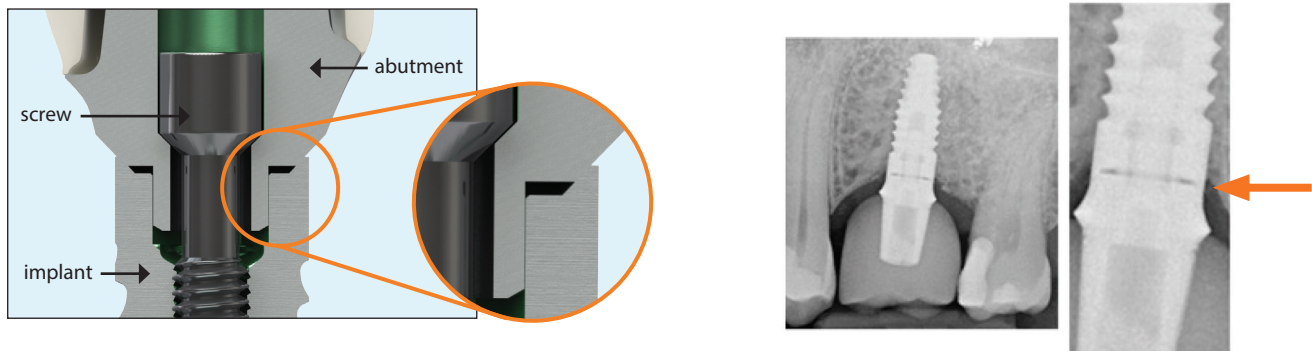


Figure 4: Cross sections (left images) show a conical seal is created by the mating of the outer bevels. X-rays (right images) show the engineered space and closed outer bevel that indicates proper abutment seating.

BioHorizons manufactures over a million components every year.⁴ With manufacturing quantities of this magnitude, maintaining engineering tolerance limits is critical to consistently ensure proper component compatibility. To dependably create the intended biologic seal at the perimeter between the implant and the abutment, an engineered space is created between the components (Figure 4). This space ensures there is contact between the implant and abutment around the entire perimeter bevel where it is most beneficial for stress transmission

and abutment screw protection. Many studies have shown that stress on an implant system is mostly concentrated at the implant-abutment connection around the abutment screw area.^{9,10} Due to the small cross-section and the pre-load induced by tightening (which causes tensile stresses in the body of the screw from the neck through the threaded area), the abutment screw is a weaker component in an implant construct.¹¹ Thus, a strong conical connection design is necessary to help protect the screw from any loosening or fracture.

Intimate contact between the implant and abutment around the entire perimeter bevel also creates a biologic seal (Figure 5). If the perimeter of the connection is sealed and has no gap, then the abutment is fully seated. It is normal to see a space on the floor of the connection and at the inner aspect of the bevel. This is to allow for normal, machining tolerances over millions of parts. If these areas were designed to bottom out, a micro-gap could be created at the outer bevel. The current design greatly minimizes the chances that a micro-gap is created. Some implant manufacturers attempt to design simultaneous contact between two surfaces (e.g., the hex flat and the perimeter bevel of the implant and

abutment) on their implant system. However, simultaneous contact of two separate surfaces in a connection is only possible with matched pairs (two unique components that only fit each other). As a result, implant designs that attempt to achieve this will create fit variability across the population of implants and abutments. A minute misfit between the implant body and abutment can cause compressive and traction forces to be directed to the restoration, resulting in prosthesis and screw loosening. According to literature, a perfect fit does not exist, but a well-engineered contact between the abutment and implant platform can reduce the load applied on the screw and significantly increase components' efficiency.¹²

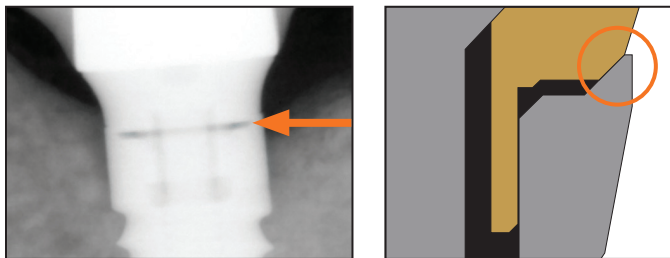


Figure 5: Internal connection showing a closed biologic seal at the outer bevel.

2. Conical connection between the abutment and the abutment screw

The second alignment feature of the BioHorizons conical connection that minimizes eccentric loading is between the abutment and the abutment screw. Figure 6 illustrates a competitive internal hex connection where the components are not properly seated. Area 1 of Figure 6 shows a single point of contact between the screw and the abutment compared to a uniform contact between the BioHorizons screw and abutment (Figure 7). The screw seat of the competitive system is interrupted by an internal thread that compromises the clinical seal and the connection. Eccentric screw loading and horizontal screw shifting may lead to screw loosening, which in turn may cause screw and/or abutment hex fracture. To compensate for this misalignment, a tapered area 3 is designed. However, if area 3 between the implant and

abutment is locked prior to full contact at area 2, bacterial infiltration could occur causing inflammation and infection at the intersection. In order to overcome these issues, BioHorizons incorporates an alignment feature between the abutment and abutment screw (Figure 7). This alignment centers the abutment screw in the connection and creates a second conical seal. Centering of the abutment screw minimizes eccentric loading during screw tightening and maximizes the clamp load created by the abutment screw.

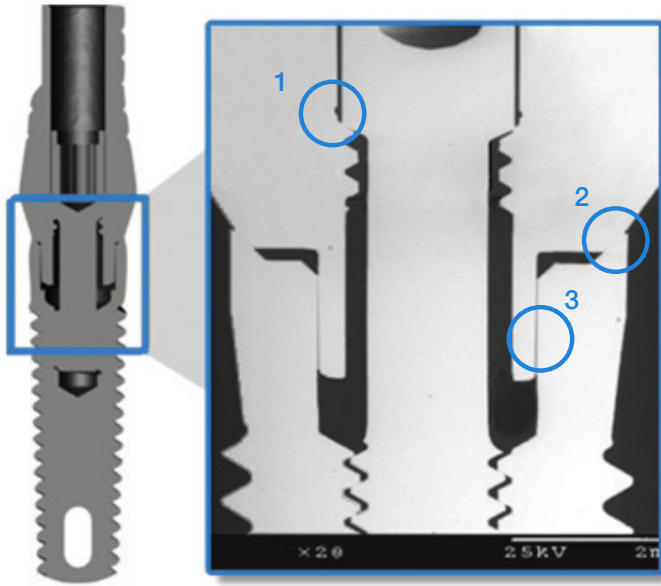


Figure 6: Competitive internal hex connection with (1) single point contact at the abutment and abutment screw; and an irreproducible, simultaneous contact at the outer level (2) and the hex flats (3).

These two alignment features are key to the BioHorizons Internal connection. Their combination provides a precision fit and predictable seal to isolate the inside of the implant from the oral and biological

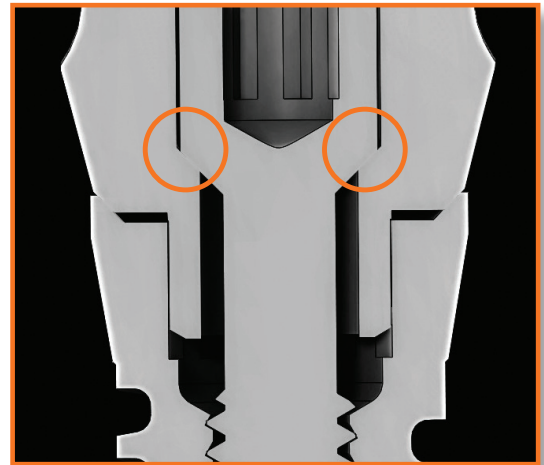


Figure 7: BioHorizons' uniform contact between the abutment and abutment screw centers the abutment screw and creates a second conical seal.

environment. More importantly, they create a more fatigue resistant joint and reduce the likelihood of screw loosening and subsequent failure.^{13,14}

Bolt Torque and Length

In a dental implant, the abutment screw acts like a very stiff spring that compresses the abutment and implant together. As the abutment screw is tightened, it stretches and creates a compressive force between the abutment and

implant (Figure 8). This force is defined as the clamping force. The spring constant of an elastic member such as a bolt is the ratio between the force applied to the member and the deflection produced by that force:¹⁵

Equation 1	$F=kx$	Where F - Clamping force k - Spring constant of the abutment screw x - Elongation of the abutment screw
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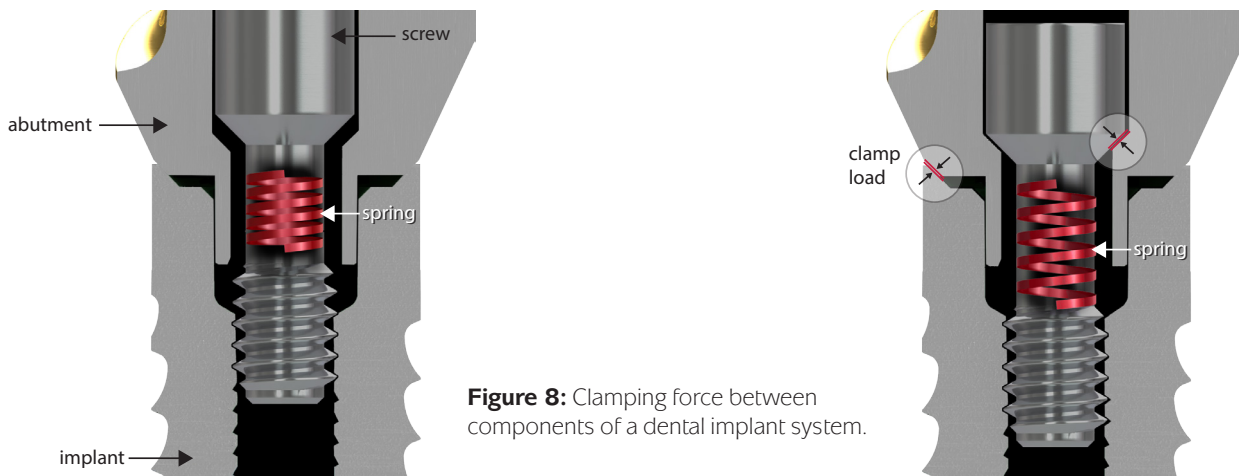


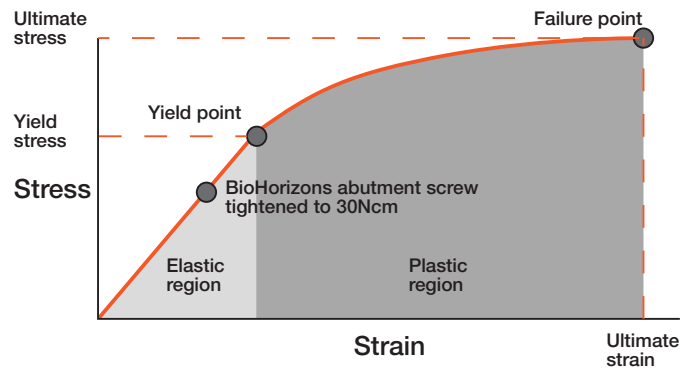
Figure 8: Clamping force between components of a dental implant system.

In order to achieve the highest clamping force during bolt tightening, it is important to minimize the effective length of the bolt (or screw) in the connection. When the length of the bolt is decreased, both its rigidity and clamping efficiency increase. Thus, bolt concentricity is maintained and eccentric loading is avoided.

It is important to properly tighten a joint so that the clamping force is maximized without overloading or yielding the screw. In other words, the screw must be tightened within

the elastic zone of the screw material. The ultimate strength is the maximum stress that a material can withstand in tension. The yield strength is the stress at which the implant starts to plastically deform (Figure 9). After the yield point, the deformation becomes permanent and non-reversible. The final abutment screw torque value for all BioHorizons conical, internally hexed implants is 30 Ncm which produces proper bold load without exceeding the yield point of the material.

Figure 9: Tightening a BioHorizons abutment screw to 30 Ncm provides a high clamping force but keeps stresses below the yield point of the material where plastic deformation could occur.¹⁶



Spiralock® Technology

Spiralock® is a superior fastening technology ideally suited for threaded joint applications subjected to heavy shock and vibration, extreme temperatures, long hours of strenuous operation, and millions of loading cycles.¹⁷ This proprietary internal thread form, used in orthopedics and the aerospace industry, is incorporated in all BioHorizons Implants and features a unique 30° wedge ramp at the root of the thread that locks the abutment screw securely to the implant, and spreads the load throughout the entire threaded connection (Figure 10). The Spiralock® thread configuration provides numerous advantages over standard thread designs:

1. Superior resistance to dynamic loading
2. Improved joint integrity
3. More evenly distributed load
4. Consistent reusability
5. Elimination of secondary locking devices

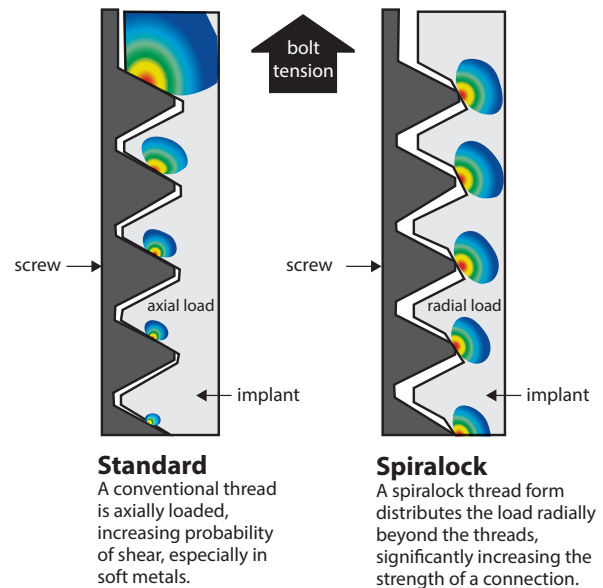


Figure 10: Comparison of load distribution between a Standard V-Thread and Spirallock®. The dark gray component represents the abutment screw and the light gray component the implant.¹⁷

A conventional abutment screw V-thread is axially loaded versus a Spiralock® thread form that distributes the load radially. This uniform thread loading reduces load and stress concentration at the first engaged thread, significantly increases the strength of the connection and prevents fatigue failure.

Platform Color Coding

All authentic BioHorizons prosthetic components and implant connections are color-coded (Figure 11) through an anodizing technique that increases the thickness of the natural oxide layer on titanium and alters its perceived color to specific hues. Color coding the surgical and restorative workflow makes it very easy to select the proper components while placing and restoring implant systems. BioHorizons internal hex prosthetics are compatible with these BioHorizons implants: Internal, Tapered Internal, Tapered Plus, and Tapered Tissue Level. The color coding and compatibility features make the system easier to use, more versatile and reduce inventory cost for dentists and lab customers.

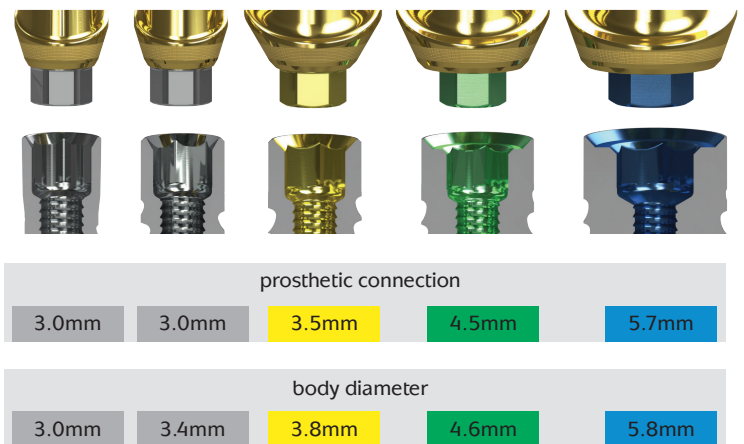


Figure 11: Color coding is used on implants, prosthetics as well as surgical, restorative and lab instrumentation.

BioHorizons Implant Materials

Fatigue testing is used in implant dentistry to determine the strength and longevity of an implant system. The governing standards are ISO 14801 – Dynamic Fatigue Test for Endosseous Dental Implants and U.S. FDA Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.^{18, 19} Generally, larger diameter implants with thicker walls have higher strength and fatigue life than smaller diameter implants of the same material.²⁰ In addition to the diameter size, the material type plays a major role in increasing the strength and fatigue limit of implants. The ability of titanium and titanium alloy to resist corrosion is a result of the formation of an insoluble and continuous titanium oxide (TiO_2) layer on the

surface (Figure 12).²¹ The titanium oxide layer prevents oxygen penetration, protects the material from any impurities and permits a compatible layer of biomolecules to attach. The excellent biocompatibility of titanium and titanium alloy is the result of the nature of this surface layer.

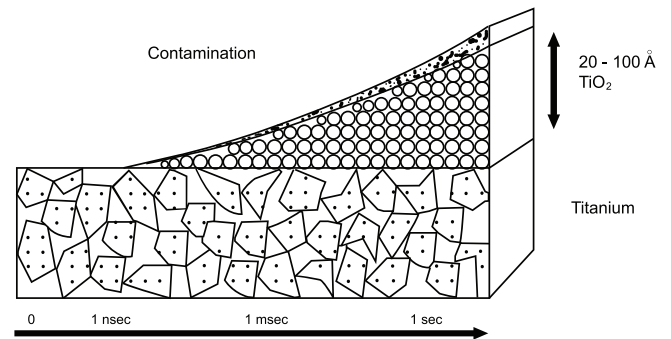


Figure 12: Formation of an insoluble titanium oxide layer on the surface of metal titanium.²¹

All BioHorizons titanium implants and prosthetic components are made from Ti-6Al-4V ELI (Grade 23), a higher-purity (“Extra- Low Interstitial”) version of Ti-6Al-4V. The lower limits of iron, carbon and oxygen (Table 1) improve ductility, fracture toughness, and fatigue crack propagation. This alpha-beta titanium alloy has superior damage and mechanical properties compared to pure titanium and standard grade Ti-6Al-4V.^{2, 22, 23}

Element	% Composition
Nitrogen	0.05 max.
Carbon	0.08 max.
Hydrogen	0.012 max.
Iron	0.25 max.
Oxygen	0.13 max.
Aluminum	5.50 - 6.50
Vanadium	3.50 - 4.50
Titanium	Balance*

Table 1: Ti-6Al-4V ELI is a higher purity version of Ti-6Al-4V for improved ductility, fracture toughness and fatigue crack propagation.

In comparison, Commercially Pure (CP) titanium comes in 4 Grades. The difference between Grade 1, which is fully annealed, and Grade 4 titanium is the amount of cold work performed to increase the strength (Table 2). While the tensile strength of CP titanium can be improved by a cold-work process, this procedure makes the material more brittle.^{24, 25} Because of the complex loading found in implant dentistry, brittle failure of higher grades of CP titanium must be considered.

	Grade 1 CP Titanium	Grade 2 CP Titanium	Grade 3 CP Titanium	Grade 4 CP Titanium	Ti-6Al-4V ELI
Ultimate Strength (MPa)	240	430	440	550	860
Yield Strength (MPa)	170-310	340	377-520	480-552	790

Table 2: Ti-6Al-4V ELI produces Ultimate Strength and Yield Strength greater than all 4 Grades of CP Titanium.^{2, 22}

*The percentage of titanium is determined by the difference

BioHorizons implant testing versus competitors

BioHorizons has completed a number of fatigue tests to compare implants manufactured from both Ti-6Al-4V ELI and CP titanium.²⁶ In order to illustrate worst case scenarios to governing bodies such as the FDA, small diameter implants are tested. Smaller diameter implants tend to have less resistance to mastication forces due to their reduced wall thickness. The following small diameter implants were tested using identical boundary conditions and a test configuration that meets the ISO 14801 standard:

1. BioHorizons® Laser-Lok® 3.0 Implants (Figure 13)²⁷
2. Nobel Biocare® NobelActive® 3.0 Implants (Figure 14)²⁸
3. Astra Tech™ OsseoSpeed™ 3.0 Implants (Figure 15)²⁹
4. Dentsply® Xive® 3.0 Implants (Figure 16)³⁰



Type of Material	Abutment Screw Torque
Ti-6Al-4V ELI	30 Ncm

Figure 13: BioHorizons® Laser-Lok® 3.0, 3.0x15mm implant with the Laser-Lok® 3.0 straight abutment



Type of Material	Abutment Screw Torque
CP Titanium	15 Ncm

Figure 14: Nobel Biocare® NobelActive® 3.0, 3.0x15mm implant with the narrow profile abutment with screw conical connection 3.0, 9mm



Type of Material	Abutment Screw Torque
CP Titanium	15 Ncm

Figure 15: Astra Tech™ OsseoSpeed™ 3.0 S, 15mm implant with TiDesign™ 3.0, D4.0, 1mm



Type of Material	Abutment Screw Torque
CP Titanium	14 Ncm

Figure 16: Xive® D3.0/L11 implant system

After connecting the implants and abutments and tightening the screw according to the Instructions For Use (IFU) of each company, static and fatigue tests were performed on the implant/abutment assemblies using MTS 858 Bionix testing systems.

A holding fixture was used to clamp the implants at a distance of 3.0 ± 0.5 mm below the implant-abutment interface. This distance is required to represent possible bone loss per ISO 14801. The clamped assemblies were held so that the implant's long axis was 30° off-angle from the loading direction. The loading force was applied through the sphere center of a hemispherical end cap placed over the free end of the abutment such that the distance from the sphere center to the clamping plane equaled 11 mm. A fixture was used to create point contact at the junction of the holding member and the testing machine so that the implant-abutment assembly was subjected to both compressive and lateral forces with no lateral constraint. Compression-to-failure tests were performed at a continuous rate of .05 in/min in air at $20 \pm 5^\circ$ C.

For the compression fatigue tests, the implant-abutment assemblies were cyclically loaded in air at a frequency of 15 Hz until failure of the assemblies or successful completion of five million cycles (i.e. a runout). The load of each fatigue test was varied in a sinusoidal manner between the nominal peak value and 10% of this value. Figure 17 summarizes the load versus number of cycles of the implant systems.

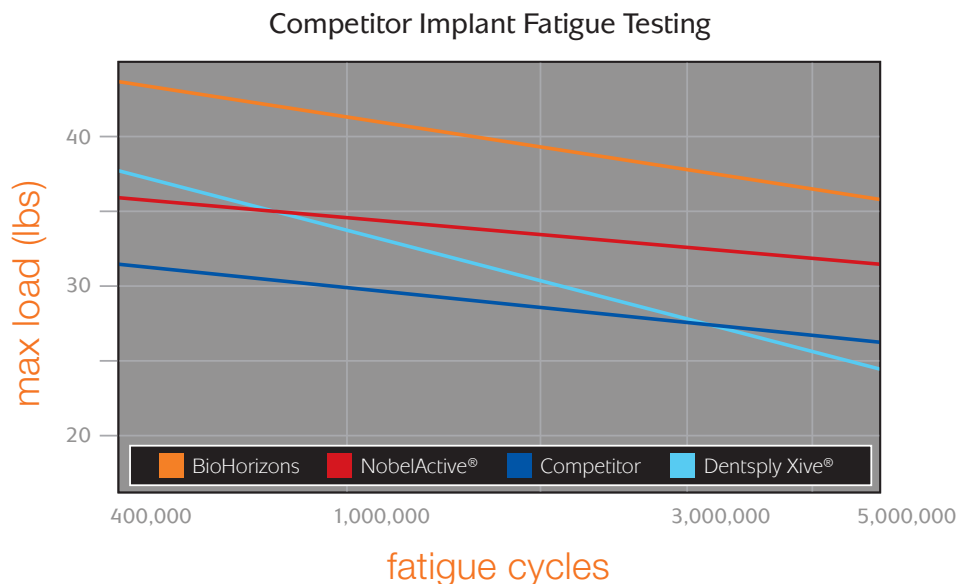


Figure 17: Load versus number of cycles for different small diameter implant systems. The BioHorizons 3.0 implant system demonstrated highest fatigue strength and runout.

Summary

Conical, internal connections have shown superior results compared to other connections regarding stability, anti-rotational engagement, tolerance to lateral forces, abutment screw loosening, screw fracture, subcrestal placement, esthetic results and ability for platform switching.³¹ BioHorizons unique, conical internal hex connection offers a number of design advantages focused on strength, durability and usability and has been proven in over 2 million implants sold to date. It combines consistently tight tolerances and creates a biologic seal that minimizes the micro-gap issues often seen with other systems. The beveled restorative platform provides an excellent biological seal at the implant-abutment interface and aids in distributing lateral load away from the abutment hex and the abutment screw.

Abutment screw loosening is avoided by the Spiralock® thread design, the same design used in orthopedics and the aerospace industry. The BioHorizons Tapered family of implants offers a wide variety of body sizes and designs to provide the flexibility of two stage, one stage, or immediate load treatment plans as well as platform-switched, platform-matched, bone level and soft tissue level placement. BioHorizons prosthetics, instruments and implants are conveniently color-coded for proper component sizing, mating and usage. These features, combined with a high strength titanium-alloy material, reduce the chances of a costly implant or prosthesis failure. BioHorizons implant systems demonstrate maximum performance even in worst-case clinical challenges, offering dentists the best implant system to meet their needs.

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